

REMARKS

Claims 1-54 are pending in the above-identified application. Claims 1-54 are now rejected under 35 U.S.C. § 103(a) as obvious over Turnlund and Hughes in combination. For at least the reasons stated below, Applicants respectfully submit that these claims are non-obvious in view of the cited combination. Applicant respectfully requests reconsideration of the rejection and allowance of all claims.

A. The Combination of Turnlund and Hughes Does Not Disclose or Suggest All the Limitations of the Present Claims

1. *Target Object Capable of Becoming Radioactive*

Independent claims 1, 41, 46, 47, 48, 51, 52, 53, and 54, and those claims depending from them (claims 2-30, 41-45, 49 and 50) include limitations directed to a “target object capable of becoming radioactive upon receiving the emitted x-rays.” The Office Action alleges that Turnlund discloses this limitation (Office Action, at 2), but the cited passage of Turnlund (11:62 – 12:6) merely describes embedding a graft with a radiosensitizer that is activated by an external or endovascular radiation source. Radiosensitizers are materials that make tissue more sensitive to radiation, and are not radioactive materials themselves. (*See* Attachment A hereto, MERRIAM-WEBSTER’S MEDICAL DICTIONARY, definition of “radiosensitizer.”) Radiosensitizers are not target objects that are capable of becoming radioactive upon receiving emitted x-rays.

Moreover, the stents or other endovascular prostheses disclosed in Turnlund are “implantable structures which can be alloyed, embedded or implanted with the proper radioactivity of radioisotopes.” (Turnlund, at 5:40-43.) By contrast, the target objects in the present application are capable of becoming radioactive upon receiving emitted x-rays. Thus, target objects of Turnlund do not receive emitted x-rays to become radioactive, as claimed in the present application, but

instead are alloyed, embedded or implanted with radioactive material. Like Hughes, which the Office Action recognizes does not disclose a target object capable of becoming radioactive upon receiving emitted x-rays, Turnlund also does not disclose the claimed target object. In the absence of this limitation, Hughes and Turnlund cannot be combined to render claims 1, 41, 46, 47, 48, 51, 52, 53, and 54, and those claims depending from them (claims 2-30, 41-45, 49 and 50) obvious.

2. *Relative Positioning Apparatus*

Claims 1-30 are directed toward a relative positioning apparatus. The Office Action concedes that Turnlund fails to disclose a system with a relative positioning apparatus. (Office Action, pg. 2.) The Office Action alleges that Hughes discloses a relative positioning apparatus operable to translate the target object relative to the x-rays. In Hughes, however, the alignment occurs by translating the radiation source. (Hughes, abstract.) In marked contrast, the relative positioning apparatus in the present claims requires translation of the target object, and not the radiation source. As such, Hughes and Turnlund cannot combine to encompass all the limitations of claims 1-30. Accordingly, claims 1-30 should be allowed for this separate and independent reason.

3. *Linear Accelerator Having An "X-ray conversion target"*

Similarly, independent claims 31, 41, 46, 47, 51, 52, 54, and the claims depending from them (claims 32-40, 42-45, 49 and 50) comprise limitations directed to an x-ray conversion target in a rotatable carousel. Neither Hughes nor Turnlund disclose an x-ray conversion target placed in a carousel. As mentioned above, the target objects in Hughes reflect infrared light for imaging. (Hughes, at 4:18-23.) The system of Hughes applies radiation directly from a radiation source to a patient (*see* Hughes, at 3:15-35 & 5:49-51). Thus, in addition to its other shortcomings, Hughes does not disclose an x-ray source for emitting x-rays from an electron beam, such as a linear accelerator

impinging upon an x-ray conversion target placed in a rotatable carousel. As noted below, neither Hughes nor Turnlund even disclose a rotatable carousel. Accordingly, claims 31-47, 49, 50-52, and 54 are all novel and non-obvious based on at least this limitation.

4. *“Means for shaping said x-ray beam”*

In addition to the other patentably distinct limitations of claim 3, the claim includes as a limitation a “means for shaping the x-ray beam.” The Office Action states that Turnlund discloses “a medical stent that has a means for shaping the x-ray beam (figure 2).” (Office Action, pg. 2.) However, Figure 2 depicts a fragmentary top perspective view of an aneurysm incorporating a stent. Applicant respectfully requests clarification on where Turnlund discloses a medical stent that has a means for shaping the x-ray beam in Figure 2. Additionally, Hughes also does not disclose a means for shaping the x-ray beam, but instead only discloses that x-ray radiation may be used to irradiate a patient. (Hughes, at 3:9-15.) Thus, claim 3 is patentable based on this limitation as well as for the other novel and non-obvious limitations it contains.

5. *Rotatable Carousel*

Claims 5, 6, 31-40, 46, 50 and 53, and claims depending from them, include limitations directed to a “rotatable carousel” that can retain “target objects” for being “impinged upon” by x-rays. The Office Action relies solely upon Figure 3 of Hughes for this limitation, but Figure 3 merely discloses an applicator 20 “including four targets 22, 24, 26, and 28.” (Hughes, at 3:35.) Instead of rotating, applicator 20 remains fixed relative to the target patient. (Hughes, at 5:1-3.) Further Hughes does not disclose a rotatable carousel at least a portion of which receives at least a portion of said x-rays. As noted above, the Hughes targets do not receive x-rays and are not capable of becoming radioactive, but instead are “imaged in order to calculate the spacing and the alignment of the radiation applicator relative to (the radiation source).” (Hughes, at 3:42-45.) Turnlund also

does not disclose a rotatable carousel. For these reasons, as well as for the other patentable distinct limitations in these claims, claims 5, 6, 31-40, 50, and 53 should be allowed.

6. *“Tube assembly having a stationary member” or “tube assembly having a substantially stationary tube” and a “translation assembly for moving the target object along a path” “positioned such that the target object receives said x-rays”*

Claims 7 and 13, and the claims depending from them (claims 8-12), have claim limitations directed either to a “tube assembly having a stationary member” or a “tube assembly having a substantially stationary tube.” In either case, the target is moved within the tube assembly such that the target receives x-rays from the x-ray source. The Office Action again points to Figure 3 of Hughes to satisfy this limitation, but there is absolutely no hint here of a “tube assembly” that allows for the translation of the target object therein such that it receives x-rays. Further, nowhere does Hughes disclose that applicator 20 has a translation assembly for moving at least one target object within a stationary member or on a path impinged upon by x-rays from an x-ray source. Targets 22, 24, 26, and 28 are not moved in a path impinged upon by x-rays from an x-ray source. Hughes discloses that the radiation beam travels through a beam inlet end and a beam outlet 56 (Hughes, at 4:38-44.) Figure 3 (Hughes) demonstrates that targets 22, 24, 26, and 28 are outside the radiation path traveling through outlet 56. Moreover, Hughes discloses no element that moves a target object within a stationary member. By contrast, the object receiving radiation in Hughes, i.e., a patient, is not moved within applicator 20, but instead, applicator 20 is inserted into the target patient. (Hughes, at 3:29-30.) As such, Hughes and Turnlund do not disclose a tube assembly, a stationary member or a translation assembly and therefore they do not render claims 7-13 obvious.

7. *“An electron beam that is directed perpendicular to the axis of rotation of the rotatable carousel”*

Claims 33 and 53, and the claims depending from them (claims 34-35), include a limitation that “an electron beam is directed perpendicular to the axis of rotation of the rotatable carousel.” The Office Action points to Figure 2 of Hughes as purportedly disclosing this limitation. As noted above, Hughes discloses no rotatable carousel, and therefore does not anticipate these claims. Moreover, the Office Action refers to Figure 3 (applicator 20) as disclosing a rotatable carousel. As applicator 20 of the Hughes patent is fixed, it has no axis of rotation perpendicular to an electron beam. Likewise, Turnlund also does not disclose an electron beam that is directed perpendicular to the axis of rotation of the rotatable carousel. These claims are accordingly patentably distinct over the cited references because of this limitation and other patentably distinct limitations.

8. *Other limitations contained within the dependent claims*

In addition to the unsupported assertion that Figure 3 contains a “rotatable carousel,” and “tube assemblies,” and electron beams directed perpendicular to the axis of rotation of the rotatable carousel, there are a number of other limitations that are generally referred to as being described in the Figures. Applicants dispute each of these allegations, but given that Applicants have already articulated numerous bases of patentability of all the rejected claims, Applicants simply demand that if these limitations are maintained as being provided by the reference, the Office is obliged to point out specifically where these limitations are disclosed. These limitations include the following:

“a fixed positioning member retaining at least one target object in generally fixed relation to said x-ray source while positioned in the path of said x-rays.” (claim 21)

“a chamber downstream of the x-ray source, the chamber including a target object entry port and wherein the relative positioning apparatus includes a translation armature extendable through the target object entry port.” (claims 29-30)

B. No Motivation to Modify Turnlund, or to Combine Turnlund with Hughes

There is no motivation to modify the Turnlund or Hughes references to read on the present claims. The prior art must suggest the desirability of the claimed invention. MPEP §2143.01. Here, the Turnlund reference discloses a method for treating aneurysms by promoting and increasing the rate of proliferative cell growth of a selected region of cellular tissue. (Turnlund, at 2:28-32.) By contrast, the present application provides an apparatus for irradiating target objects such that the target objects become radioactive upon receiving x-rays. As noted above, the radiosensitizers disclosed in Turnlund do not emit radioactivity. The stents and other endovascular prostheses in Turnlund do not become radioactive upon receiving emitted x-rays, but are instead objects in which radioactive material is implanted, alloyed or embedded. The external source of radiation relied upon in Turnlund (Turnlund, at 12:3-6) merely activates radiosensitizers in order to make surrounding tissue more sensitive to radiation. Nothing in Turnlund suggests developing a system that irradiates a target object that becomes radioactive itself upon receiving x-rays. Thus, no motivation exists to modify Turnlund to produce the presently recited claims.

Similarly, there is no motivation to combine Turnlund with Hughes. Neither Hughes nor Turnlund describes a system or method of causing an object to become radioactive. While Hughes provides an alignment system for directing radiation into a patient, Hughes does not disclose making the patient radioactive. Nothing in Hughes or Turnlund suggest that combining an alignment system with radiosensitizers that do not become radioactive or with radio-alloyed stents will cause an object to become radioactive itself upon receiving x-rays. Thus, there is no suggestion or motivation to

combine Hughes with Turnlund to encompass all the limitations in the present claims. Accordingly, the combination is improper, and claims 1-54 should be allowed for this reason in addition to the fact that the cited combination does not disclose all of the limitations of the claims.

C. A Bare Statement of Obviousness is Insufficient to Establish a Prima Facie Case

The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of non-obviousness. Here, bare statements of obviousness are made which are insufficient to establish a prima facie case. MPEP § 2142.

Regarding claim 14, the Office Action concedes that Hughes fails to teach a sensor that measures parameters selected from a group including electron beam current, temperature monitoring device, and a radiation detector and a control circuit controlling the electron beam provided by the electron beam source based on the parameters measured by at least one sensor. Thus, by the Office Action's own admission, claim 14 distinguishes from Hughes. Likewise, Turnlund also does not disclose the aforementioned limitations. The Office Action's bare statement that these limitations would have been obvious to one of ordinary skill in the art is insufficient to meet the burden of establishing a prima facie case of obviousness. As claims 15-18 all depend from claim 14, they also distinguish from Hughes and Turnlund. Moreover, claims 15-18 contain limitations that further distinguish from Hughes and Turnlund. For example, claim 15 recites "at least one sensor includes a radiation detector situated downstream of said relative positioning apparatus." As noted above, neither Hughes nor Turnlund disclose a relative positioning apparatus. As another example, claim 16 recites "at least one sensor includes a metering circuit measuring the electric current received in said x-ray conversion target." This limitation is not disclosed or suggested by Hughes or Turnlund. For these reasons, none of claims 14-18 are obvious in view of Hughes or Turnlund.

RESPONSE TO OFFICE ACTION

therefore request that the rejection of these claims be reconsidered and withdrawn.

Regarding claim 24, the Office Action concedes that Hughes fails to disclose the relevant limitations: the use of a heat transfer system that includes a conduit for conveying a heat transfer fluid. Instead, the Office Action merely relies on the unsupported statement that the requirements of claim 24 would have been obvious to one of ordinary skill in the art. These unsupported statements are insufficient to establish a prima facie case of obviousness. Likewise, Turnlund also does not disclose the use of a heat transfer system that includes a conduit for conveying a heat transfer fluid. For these reasons, claim 24 is not obvious in view of Hughes or Turnlund. Because claim 25 depends from claim 24, it distinguishes from Hughes and Turnlund for the same reasons. Moreover, claim 25 adds further limitations that distinguish it from Hughes and Turnlund. Applicants therefore request that the rejection of claims 24 and 25 be reconsidered and withdrawn.

Regarding claim 26, the Office Action again relies on the bare argument that “[it] would . . . be obvious to one skilled in the art to utilize a thermal shield.” Although, the Office Action describes the rationale for this argument as “the temperatures induced by a linear accelerator are substantial, and require a thermal shield,” the Office Action presents no support for this statement. Moreover, the Office Action presents no arguments regarding the positioning of the heat shield. For these reasons, the Office Action has failed to establish a prima facie case of obviousness of claim 26. Applicants therefore request that the rejection of claim 26 be reconsidered and withdrawn.

Regarding claim 27, the Office Action again concedes that Hughes fails to disclose a target with a plurality of layers wherein at least a first one of the layers comprises x-ray generating material, and electron absorption capability. Instead, the Office Action merely relies on the unsupported statement that “[i]t would be inherent in the art to utilize material in a target with x-ray generating material, and one would desire electron absorption in order to minimize scatter.” These unsupported

statements are insufficient to establish a prima facie case of obviousness. Moreover, the Office Action fails to establish that all of the limitations of claim 27 are disclosed or suggested by the prior art, including Turnlund. For these reasons, claim 27 is not obvious in view of Hughes and Turnlund. Because claim 28 depends from claim 27, it distinguishes from Hughes and Turnlund for the same reasons. Applicants therefore request that the rejection of claims 27 and 28 be reconsidered and withdrawn.

The Office Action does not articulate a basis upon which the subject matters of amended claims 34, 35, 38 and 39 as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. Accordingly, the Office Action has failed to establish a case of prima facie patentability. In spite of this, Applicants submit that neither Hughes nor Turnlund disclose or suggest the limitations of amended claims 34, 35, 38 and 39. As noted above, Hughes and Turnlund do not disclose a rotatable carousel, a target object, or an x-ray conversion target. As such, Hughes and Turnlund fail to disclose each and every limitation in amended claim 31, the parent claim to claims 34, 35, 38 and 39. One of ordinary skill in the art would not be motivated to incorporate a rotatable carousel, a target object, or an x-ray conversion target with the other limitations recited in claim 31. Because Hughes or Turnlund do not disclose these elements, and one skilled in the art would not be motivated to incorporate these elements in claim 31, it is not obvious in view of Hughes or Turnlund. Thus, because claims 34, 35, 38 and 39 depend from claim 31, there are similarly not obvious in view of Hughes and Turnlund. Applicants therefore request that rejection of claims 34, 35, 38 and 39 under 35 U.S.C. § 103(a) in view of Hughes and Turnlund be reconsidered and withdrawn.

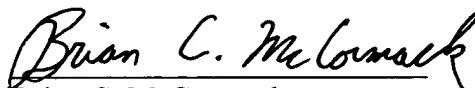
CONCLUSION

For a finding of obviousness, the combination of Hughes and Turnlund must disclose each and every limitation of the claims. As noted above, one or more limitations of all the claims, including claims 1-54, are not disclosed in Hughes or Turnlund. Further, there is no suggestion to combine these references, and many of the Office Action's statements fail to raise a prima facie case of unpatentability. For at least these reasons, Applicants respectfully requests reconsideration, and submits that the combination of Hughes and Turnlund does not render claims 1-54 obvious. Withdrawal of the rejection and allowance of all claims is respectfully requested.

This Response to Office Action cancels no claims and adds no new claims. Accordingly, no claims fees are required by the filing of this document. In the event, however, that any fees are required to cover the cost of this filing, the Commissioner is authorized to charge those fees, or credit any overpayment, to Account No. 13-0480, Attorney Docket No. 67110070.1003.

If the Examiner has any questions regarding this Response to Office Action or the Application in general, the Examiner is invited to contact the Applicants' attorney at the below-listed telephone number.

Respectfully submitted,



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Merriam-Webster's Medical Desk Dictionary

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radiosensitizer

noun : a substance or condition capable of increasing
the radiosensitivity of a cell or tissue radiosensitization
noun radiosensitizing adjective

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Attachment A